**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**
**CHARLESTON DIVISION**

**In Re: Boston Scientific Corp.**
**Pelvic Repair System**
**Products Liability Litigation**

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| BERTIE FRANKUM,<br><br>Plaintiff,<br><br>v.<br><br>BOSTON SCIENTIFIC CORP. and JOHN DOES 1-10, being any other company that designed, manufactured, and/or marketed the medical device inserted in Plaintiff Bertie Frankum which forms the basis of this Complaint,<br><br>Defendants. | ) | 2:12-0904<br><br>**MDL No. 2326** |

## COMPLAINT

Plaintiff BERTIE FRANKUM hereby complains and alleges against Defendant BOSTON SCIENTIFIC CORP. ("BSC") and Defendant JOHN DOES 1-10 ("Doe Defendants") (BSC and the Doe Defendants will be collectively referred to as "Defendants") as follows:

### PARTIES, JURISDICTION AND VENUE

1.

Plaintiff is a citizen of the State of North Carolina.

2.

Defendant BSC is a corporation organized and existing under the laws of Delaware with its principal place of business located at 1 Boston Scientific Place, Natick, Massachusetts, 01760-1537. BSC is and has been at all times pertinent to this proceeding engaged in the design and manufacturing of medical technologies used by urologists and urogynecologists to diagnose and treat a variety of urologic conditions, including, but not limited to, stress urinary incontinence and pelvic organ prolapse. BSC marketed, packaged, labeled, and sold the medical device at issue in this lawsuit.

3.

The Doe Defendants are and have been at all times pertinent to this proceeding engaged in the design and manufacturing of medical technologies used by urologists and urogynecologists to diagnose and treat a variety of urologic conditions, including, but not limited to, stress urinary incontinence and pelvic organ prolapse. The Doe Defendants marketed, packaged, labeled, and sold the medical device at issue in this lawsuit. Plaintiff is unaware of the true names and capacities of the Doe Defendants sued herein as John Does 1-10, inclusive, and therefore sues these Doe Defendants by such fictitious names. Plaintiff will amend this complaint to allege the Doe Defendants' true names and capacities when ascertained. Plaintiff will exercise due diligence to determine Doe Defendants' true names, capacities, and contact information, and to effect service upon those Doe Defendants.

4.

A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the Western District of North Carolina.

5.

The subject matter of this Complaint is also the subject matter of multi-district litigation commenced pursuant to 28 U.S.C. §1407 in MDL No. 2326 in the Southern District of West Virginia. The presiding Judge is U.S. District Judge Joseph R. Goodwin. Personal jurisdiction and subject matter jurisdiction are appropriate in this court as to BSC, pursuant to Pre-Trial Order No. 1, as BSC has availed themselves of this jurisdiction and venue.

6.

The Defendants have been and/or currently are engaged in business, directly or by authorized agent, in Cleveland County, North Carolina. Venue and jurisdiction are therefore proper, as to this Plaintiff, in the United States District Court for the Western District of North Carolina and in MDL No. 2326 in the Southern District of West Virginia. The claims of the Plaintiff herein satisfy the jurisdictional amount of this Court.

7.

By directly filing this Complaint in MDL No. 2326 in the Southern District of West Virginia, Plaintiff does not waive her right to trial in the United States District Court for the Western District of North Carolina. Plaintiff seeks remand to the Western District of North Carolina for the trial of this case.

FACTUAL ALLEGATIONS

8.

Plaintiff Bertie Frankum was implanted with the Obtryx Transobturator Sling System on February 9, 2009 during surgery performed by Dr. Shem Blackley, III. The System ("the Product") included the surgical mesh sling as well as instruments to aid in the placement of the

sling. The procedure was performed at Cleveland Regional Medical Center in Shelby, North Carolina.

9.

The Product was implanted in the Plaintiff to treat her stress urinary incontinence, the use for which the Product was designed, marketed, and sold.

10.

Defendant BSC and/or the Doe Defendants manufactured, marketed, packaged, labeled, and sold the Product implanted in the Plaintiff.

11.

As a result of having the Product implanted in her, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, will likely be forced to undergo corrective surgery, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses.

## CAUSES OF ACTION

### COUNT I: NEGLIGENCE

12.

Plaintiff incorporates by reference paragraphs 1-11 of this Complaint as if fully set forth herein.

13.

Defendants had a duty to individuals, including the Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Product.

14.

Defendants were negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling, packaging, and selling the Product.

15.

As a direct and proximate result of Defendants' negligence, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

16.

Plaintiff incorporates by reference paragraphs 1-15 of this Complaint as if fully set forth herein.

17.

The Product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as a matter of law with respect to its design.

18.

As a direct and proximate result of the Product's aforementioned defects, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

19.

Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling the defective Product.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

20.

Plaintiff incorporates by reference paragraphs 1-19 of this Complaint as if fully set forth herein.

21.

The Product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as a matter of law with respect to its manufacture.

22.

As a direct and proximate result of the Product's aforementioned defects, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

23.

Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling the defective Product.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

24.

Plaintiff incorporates by reference paragraphs 1-23 of this Complaint as if fully set forth herein.

25.

The Product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as a matter of law due to its lack of appropriate and necessary warnings.

26.

As a direct and proximate result of the Product's aforementioned defects, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

27.

Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging, and selling the defective Product.

## COUNT V: BREACH OF EXPRESS WARRANTY

28.

Plaintiff incorporates by reference paragraphs 1-27 of this Complaint as if fully set forth herein.

29.

Defendants made assurances to the general public, hospitals, and health care professionals that the Product was safe and reasonably fit for its intended purpose.

30.

The Plaintiff and/or her health care provider chose the Product based upon Defendants' warranties and representations regarding the safety and fitness of the Product.

31.

The Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Product was safe, merchantable, and reasonably fit for its intended purposes.

32.

Defendants breached this express warranty because the Product implanted in the Plaintiff was unreasonably dangerous and defective and not as Defendants had represented.

33.

Defendants' breach of its express warranty resulted in the implantation of an unreasonably dangerous and defective Product in the Plaintiff's body, placing the Plaintiff's health and safety in jeopardy.

34.

As a direct and proximate result of Defendants' breach of the aforementioned express warranty, the Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

## COUNT VI: BREACH OF IMPLIED WARRANTY

35.

Plaintiff incorporates by reference paragraphs 1-34 of this Complaint as if fully set forth herein.

36.

Defendants impliedly warranted that the Product was merchantable and was fit for the ordinary purpose for which it was intended.

37.

When the Product was implanted in the Plaintiff to treat her stress urinary incontinence, the Product was being used for the ordinary purpose for which it was intended.

38.

The Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranty of merchantability in consenting to have the Product implanted in her.

39.

Defendants breached this implied warranty of merchantability because the Product implanted in the Plaintiff was neither merchantable nor suited for its intended use as warranted.

40.

Defendants' breach of their implied warranty resulted in the implantation of an unreasonably dangerous and defective Product in the Plaintiff's body, placing the Plaintiff's health and safety in jeopardy.

41.

As a direct and proximate result of Defendants' breach of the aforementioned implied warranty, the Plaintiff was caused and/or in the future will be caused to suffer severe personal

injuries, pain and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

COUNT VII: PUNITIVE DAMAGES

42.

Plaintiff incorporates by reference paragraphs 1-41 of this Complaint as if fully set forth herein.

43.

Defendants knew or should have known that the Product was defective and presented unreasonable risks or harm to the Plaintiff.

44.

Defendants sold the Product to the Plaintiff's health care providers and other health care providers in North Carolina and throughout the United States without doing adequate testing to ensure that the Product was reasonably safe for implantation in the female pelvic area.

45.

Defendants sold the Product to the Plaintiff's health care providers and other health care providers in North Carolina and throughout the United States without doing adequate testing to determine whether the Product degraded in vivo. The Product, does, in fact, degrade in vivo, which causes the severe and debilitating injuries suffered by the Plaintiff and numerous other women.

46.

Defendants ignored reports from health care providers throughout the United States of the Product's failures to perform as intended, which lead to the severe and debilitating injuries

suffered by the Plaintiff and numerous other women. Rather than doing adequate testing to rule out the Product's design or the process by which the Product is manufactured as the causes of these severe and debilitating injuries, Defendants chose instead to instruct their sales forces to downplay the Product's risks, and have continued to market and sell the Product as a safe and effective way to treat stress urinary incontinence.

47.

Defendants' conduct as described in this Complaint, for which the Plaintiff is entitled to recover compensatory damages, manifested a conscious indifference to, and/or flagrant disregard of, the safety of those persons who might foreseeably have been harmed by the Product, including the Plaintiff, justifying the imposition of punitive damages.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

a. compensatory damages on each cause of action;

b. punitive damages on each cause of action;

c. reasonable attorneys' fees where recoverable;

d. costs of this action; and

e. such other additional and further relief as the Court may deem necessity, appropriate, and just.

**DEMAND FOR JURY TRIAL**

Plaintiff demands a trial by jury on all counts and issues.

/s/Wesley Chadwick Cook
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